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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,129	03/23/2006	Hansell H Stedman	UPNQ3278USA	8761

270 7590 08/31/2010

HOWSON & HOWSON LLP
501 OFFICE CENTER DRIVE
SUITE 210
FORT WASHINGTON, PA 19034

EXAMINER	
OSINSKI, BRADLEY JAMES	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
08/31/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@howsonandhowson.com

Office Action Summary	Application No.	Applicant(s)	
	10/573,129	STEDMAN ET AL.	
	Examiner	Art Unit	
	BRADLEY J. OSINSKI	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7-8-2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 34-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daneshvar (5,728,066).

a. Regarding claim 34, Daneshvar discloses a flexible elongate cannula 35 having distal and proximal ends and extending along an axis with an internal channel for the application of fluid (Col.1, lines 10-13). An inflatable and radially expandable balloon 36 is attached to the cannula and extends from adjacent the distal end to adjacent the proximal end of the cannula. When inflated, the balloon forms an elongate, continuous and substantially cylindrical tube along its full length. While Daneshvar substantially discloses the apparatus as claimed, it does not disclose the balloon extending the length of the entire aorta. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the balloon of Daneshvar because Applicant has not disclosed that such a limitation provides an unexpected advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with Daneshvar because Daneshvar

discloses the balloon barrier being used in all portions of the aorta, including the ascending aorta, aortic arch and descending aorta (Col.17 lines 63-67). Daneshvar further discloses the balloon size, shape and location as being variable depending on intended use (Col.19 lines 11-13) and that the balloon may be adjustable to allow the position to be changed (Col.19 lines 1-3). Therefore, it would have been an obvious matter of design choice to modify Daneshvar to obtain the invention as specified in claim 34.

b. Regarding claim 35, Daneshvar discloses the catheter body may have a J-shaped ending to prevent from damaging the wall of the vessel (Col.6 lines 59-61). See claim 34 regarding elongation of the balloon. Applying a J shape to the balloon would also prevent the balloon from damaging the wall of the vessel. It would have been obvious to one of ordinary skill in the art at the time the invention was made to shape the elongated balloon of Daneshvar in a J-shape to prevent it from damaging the wall of the vessel.

c. Regarding claim 36, Daneshvar further discloses various figures showing the bend of the catheter and it being located within the aortic arch (figures 4-6 and 11-14).

d. Regarding claim 37, from figure 6 it is apparent the curve is subtending an angle of approximately 180^{o}.

e. Regarding claim 38, figure 7 shows three different lumens, one is capable of serving as a vent during vector recirculation and both tips of catheters/lumens 35 and 42 are open to a vessel lumen.

f. Regarding claim 39, while Daneshvar substantially discloses the apparatus as claimed, it does not disclose the exact measurements of the catheter. However, Daneshvar does acknowledge that the aorta size varies in different people (Col.10 lines 42-44) and that a proper curvature of the distal end is desired to place it within certain parts of the aorta (Col.17 lines 8, 22, 27 and 35). Finally, Daneshvar discloses varying the balloon size, shape and location depending on its intended use (Col.19 lines 11-13). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the curvature of the distal arc, length of the balloon envelope and diameter of the tube, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233 (CCPA 1955).*

g. Regarding claim 40, figures 6-8 show the balloon as a single, continuous balloon with uninterrupted internal space for expansion fluid.

2. Claims 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daneshvar (5,728,066) as applied to claim 40 above, and further in view of van Moorlegem et al (6,776,771).

h. Regarding claim 41, while Daneshvar substantially discloses the apparatus as claimed, it does not disclose the balloon being a series of separate balloon segments disposed end-to-end with no gaps therebetween. However, van Moorlegem discloses an adaptive balloon catheter that may be used in the

aorta (Col.1 line 55) with a series of separate balloon segments (Col.3 lines 17-19). Further disclosed is that the opposing flanges can be parallel to each other (Col.4 lines 60 and 61, and figure 1) and further discusses varying the length of hinges 7 (Col.4 lines 35-37). Thus varying the length as suggested by Daneshvar offers a finite number of options, including shortening the hinges such that there are no gaps between the balloons. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Daneshvar with separate balloon segments with no gaps therebetween as taught by van Moorlegem in order to introduce an adaptive balloon with improved flexibility.

i. Regarding claim 42, see claims 34 and 41 above. The lumen of catheter 35/45 is capable of receiving fluid under pressure.

j. Regarding claim 43, see claim 24 above.

k. Regarding claim 44, see claim 38 above.

l. Regarding claim 45, see claim 39 above.

Response to Amendment

3. The declaration under 37 CFR 1.132 filed 7/8/2010 is insufficient to overcome the rejection of claims 34 and 42 based upon their rejection under 35 USC 103 as set forth in the last Office action because: The showing is not commensurate in scope with the claims. The declaration states that modifying the catheters disclosed in the references according to the claimed invention would result in the fatality of the patient (paragraph 6). Applicant then goes on to discuss how the invention relates to gene therapy in

patients that under total circulatory arrest and hypothermic conditions (paragraphs 7 and 8) while the references are used for blood flow in a warm patient (paragraph 7). However, the claims are apparatus claims and much of this is intended use. The declaration then goes onto discuss how Daneshvar's intention is not to entirely occlude the vena cavae but to momentarily redirect blood flow through the heart while still permitting normal pulsed blood flow to travel through the heart of the warm patient (paragraph 11). However, it is only the intended use of Applicant's device that the balloon be totally inflated in a hypothermic patient to prevent cross-flow through the aorta between various branch vessels. No evidence is offered that the longer balloon suggested by the examiner needs to be completely inflated such that it completely occludes blood flow in a living patient causing death. The device is capable of use as both suggested by the reference and as intended by Applicant. The examiner believes the declaration holds merit against the use of the references in a rejection against method claims, but does hold much merit with respect to apparatus claims.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Response to Arguments

4. Applicant's arguments filed 7/8/2010 have been fully considered but they are not persuasive.

m. Applicant argues the intended use of the device (see response to declaration for example), a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior

art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

n. The Examiner is not convinced that the device of Daneshvar used as intended would result in the death of the patient. A longer balloon that only partially occludes the circulatory system continues to have the same expected results. Nowhere in Daneshvar does it say that a longer balloon must be full inflated to produce the same effects (prevent the quick washing away of injected material). Additionally, there is no requirement in the claims for how long the partial obstruction of the vessels needs to occur (and again would be intended use in these apparatus claims).

o. Nowhere in the claim is total circulatory arrest or hypothermic temperature required, other than as intended use, as continuously argued.

p. Applicant argues that it would not have been an obvious matter of design choice to enlarge the balloon since it would destroy the intent, purpose or function of the device. The Examiner disagrees, Daneshvar is very clear that the catheter and balloon may be reshaped based upon its intended use (Col.6 lines 41-43). Changing the size of the device would only change its ability to occlude/block in a predictable manner. The device of Daneshvar already solves the particular purpose and stated problem as it is capable of occluding a vessel it is inserted into, elongating it does not further solve the problem, only improve upon its abilities in a predictable manner.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY J. OSINSKI whose telephone number is (571)270-3640. The examiner can normally be reached on M-Th 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley J Osinski/
Examiner, Art Unit 3767
/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761